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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/551,738 | 02/07/2006 | Nikolay Khanzhin | 429-US-PCT | 4289 |
| 45821 | 7590 | 12/31/2008 | EXAMINER | |
| LUNDBECK RESEARCH USA, INC. ATTENTION: STEPHEN G. KALINCHAK, LEGAL 215 COLLEGE ROAD PARAMUS, NJ 07652 | | | CHU, YONG LIANG | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/31/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/551,738 | KHANZHIN ET AL. | |
| | Examiner | Art Unit | |
| | YONG CHU | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 October 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 5,8,9,11,13,14,16,19,20 and 24-37 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6,10,12,17,21 and 23 is/are rejected.
- 7) Claim(s) 1-4,6,7,10,12,15,17,18 and 21-23 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 1-37 are pending. Claims 24-37 remain withdrawn as non-elected subject matter.

Response to Amendment

The amendment by Applicants' representative Margaret M. Buck dated on 10/29/2008 has been entered.

Response to Arguments/Remarks

Elected and Examined Subject Matter

Applicant's argument on the ground that the elected and examined subject matter does not encompass Applicants' elected species because R² as halogen is not included in the examined scope of invention. Applicants' argument is persuasive. Actually, the elected species was searched, and found allowable. The search and examination had been expanded to the subject matter beyond the elected subject matter in the previous Office action. Even though the elected and examined subject matter in the previous Office action was accidentally mistaken by missing R² as halogen, the art rejection is still correct. Since Applicants' amendment has overcome the rejection (see the following section), search and examination will be expanded to part of the previously non-elected subject matter (see the new provisionally elected and examined subject matter, which encompasses the elected species and beyond).

Rejection under 35 U.S.C. §103(a)

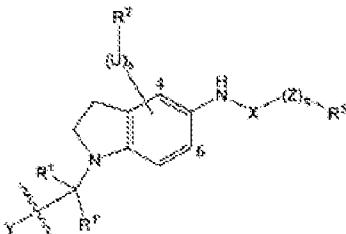
Applicant's amendment of claim 1 by deleting "the dotted line represents an optional bond" has obviated the rejection.

Claim Objection

Since Applicants' amendment has obviated the art rejection, and search and examination are expanded to previously non-elected subject matter, therefore, the claim objection for containing non-elected subject matter is moot.

Provisionally Elected and Examined Subject Matter

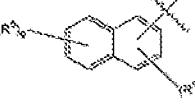
The scope of the invention which is the provisionally elected and examined is as follows:



A compound of the Formula (I) according to amended claim 1, wherein:

R¹ and **R^{1'}** are hydrogen or C₁₋₆alkyl;

R² is hydrogen or halogen; **R³** is C₁₋₆alkyl, **Ar-C₁₋₆alkyl**, or optionally substituted **NR¹²R^{12'}-C₁₋₆alkyl**, wherein **R¹²** and **R^{12'}** are each independently selected from the group consisting of hydrogen, C₁₋₆alkyl, and **Ar-C₁₋₆alkyl**;

Y is , , or , wherein **W** is -S, **R⁵** is halogen, **a** is 1, **f** is 0, **g** is 0, and **h** is 0; **X** is -CO; **q** and **s** are 0; and the remaining substituents are as defined according to claim 1, and a pharmaceutical composition comprising the compound thereof.

As a result of the election and the corresponding scope of the invention identified supra, claims 5, 8-9, 11, 13-14, 16, 19-20, and the remaining subject matter of claims 1-4, 6-7, 10, 12, 15, 17-18, and 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds and compositions contain varying functional groups which are chemically recognized to differ in structure, function, and reactivity. The scope of the invention is set in considering the elected species and the preferred embodiments. In addition, a reference, which anticipates one group, would not render obvious the other.

Therefore, claims 1-4, 6-7, 10, 12, 15, 17-18, and 21-23 will be examined on the merits.

Claim Rejections - 35 USC § 102

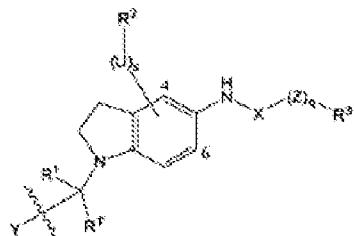
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 10, 12, 17, 21, and 23 are rejected under 35 U.S.C. 102 (b) as being anticipated by Auvin et al., WO-2000017190A2, (“the ‘190 publication”), see the corresponding *U.S. Patent No.6,653,312*.

Applicants' claims relate to a compound of the Formula (I)



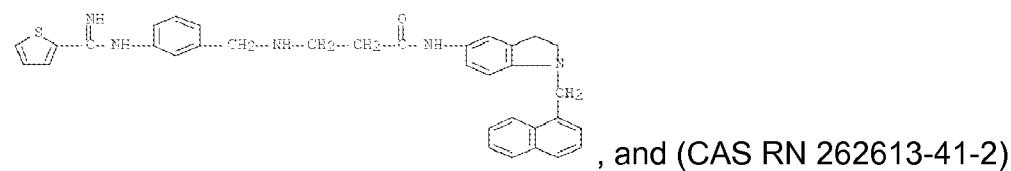
according to amended claim 1, wherein:

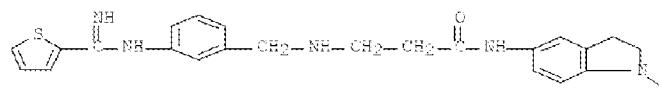
R¹ and **R^{1'}** are hydrogen or C₁₋₆alkyl;

R² is hydrogen or halogen; **R³** is C₁₋₆alkyl, **Ar-C₁₋₆alkyl**, or optionally substituted **NR¹²R^{12'}-C₁₋₆alkyl**, wherein **R¹²** and **R^{12'}** are each independently selected from the group consisting of hydrogen, C₁₋₆alkyl, and **Ar-C₁₋₆alkyl**;

Y is  ,  or  , wherein **W** is -S, **R⁵** is halogen, **a** is 1, **f** is 0, **g** is 0, and **h** is 0; **X** is -CO; **q** and **s** are 0; and the remaining substituents are as defined according to claim 1, and a pharmaceutical composition comprising the compound thereof.

The '190 publication disclosed specific compounds (CAS RN 262613-42-3)



, and (CAS RN 262613-41-2)
 found in claim 5 of the

corresponding U.S. Patent No.6,653,312, and a pharmaceutical composition comprising

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a compound thereof. These compounds or compositions anticipate the instantly claimed scope of invention, wherein \mathbf{R}^1 and \mathbf{R}^{11} are hydrogen; \mathbf{R}^2 is hydrogen; \mathbf{R}^3 is optionally substituted $\mathbf{N}\mathbf{R}^{12}\mathbf{R}^{12'}$ - $\text{C}_{1-6}\text{alkyl}$, wherein \mathbf{R}^{12} and $\mathbf{R}^{12'}$ are each independently selected from the group consisting of hydrogen, and $\mathbf{Ar}\text{-C}_{1-6}\text{alkyl}$, wherein



the substituent is 3-(imino-2-thienylmethyl)-amino- group; \mathbf{X} is -CO; \mathbf{Y} is

or , wherein \mathbf{R}^5 is halogen; \mathbf{f} is 0; \mathbf{g} is 0, and \mathbf{h} is 0; \mathbf{q} and \mathbf{s} are 0.

Claim Objection

Claims 2-4, 6-7, 10, 12, 15, 17-18, and 21-23 are objected to for depending on the rejected claim 1.

Claims 1-4, 6-7, 10, 12, 15, 17-18, and 21-23 are provisionally objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

Conclusions

- Claims 1-4, 6-7, 10, 12, 15, 17-18, and 21-23 are objected to.
- Claims 1-4, 6, 10, 12, 17, 21, and 23 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M^cKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/REI-TSANG SHIAO /

/Yong Chu,/

Patent Examiner

Art Unit 1626

Rei-Tsang Shiao

Primary Patent Examiner

Art Unit 1626